

REMARKS/ARGUMENTS

Favorable reconsideration of this application, as presently amended and in light of the following discussion, is respectfully requested.

Claims 19, 21-32, 34-36 and 42 are pending in the present application. Claims 19, 28 and 42 have been amended without the introduction of any new matter. In particular, support for a convex reference curve having a substantially uniform radius of curvature is shown in Figure 3.

In the outstanding Office Action, (I) Claims 19 and 21-30 were rejected under 35 U.S.C. § 112, first paragraph; (II) Claims 19, 21-32, 34-36 and 42 were provisionally rejected under 35 U.S.C. § 101 for double patenting; (III) Claims 19, 21-32, 34-36 and 42 were rejected under 35 U.S.C. § 102(b) as anticipated by Burkinshaw (U.S. Patent No. 6,602,292); (IV) Claims 19, 21-32, 34-36 and 42 were rejected under 35 U.S.C. § 103(a) as obvious over Burkinshaw; (V) Claims 19, 21-32, 34-36 and 42 were rejected under 35 U.S.C. § 102(b) as anticipated by Shelokov (U.S. Patent No. 6,039,763); and (VI) Claims 19, 21-32, 34-36 and 42 were rejected under 35 U.S.C. § 102(b) as anticipated by Linscheid et al. (U.S. Patent No. 5,405,400, herein “Linscheid”).

I. 35 U.S.C. § 112 Rejection

Regarding the rejection of Claims 19 and 21-30 under 35 U.S.C. § 112, first paragraph, the claims have been amended in light of the comments noted in the outstanding office action. As such, Applicants respectfully request that this rejection be withdrawn.

II. 35 U.S.C. § 101 Rejection

Claims 19, 21-32, 34-36 and 42 were provisionally rejected under 35 U.S.C. § 101, for allegedly claiming the same invention as that of co-pending patent application serial No. 11/648,384. That rejection is respectfully traversed.

Applicants respectfully submit that co-pending patent application serial No. 11/648,384 (“the ’384 application”) is a divisional of, and claims priority to, the present invention. In the Office Action dated November 19, 2007, the Examiner stated that “[n]ewly submitted claims 37-41 are directed to an invention that is independent or distinct from the

invention originally claimed . . .” (See November 19, 2007 Office Action at p. 3). In response, Applicants filed the ’384 application which was divided from the present application based on the above Examiner requirement.

The restriction of claims in a patent application to a single invention when independent and distinct inventions are presented for examination is authorized under 35 U.S.C. § 121. Under 35 U.S.C. 121 and MPEP 804, “[a] patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.”

Accordingly, it is respectfully requested that this rejection be withdrawn.

Further, patent rules also hold that a terminal disclaimer is not required in whichever of two co-pending applications first receives a notice of allowance. Thus, Applicants respectfully submit that it would also be considered premature to offer any further submission at this point. Applicants respectfully request the provisional double patenting rejection be withdrawn or held in abeyance until the Examiner has agreed to allowable subject matter in this application or in the ’384 application.

III and IV. 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) Rejections Relating to Burkinshaw

Claims 19, 21-32, 34-36 and 42 were rejected under 35 U.S.C. § 102(b) as anticipated by Burkinshaw and rejected under 35 U.S.C. § 103(a) as obvious over Burkinshaw. Those rejections are respectfully traversed.

Applicants respectfully submit that anticipation requires that each and every element of the claimed invention be found in the cited reference. Therefore, the invention, in its entirety, must be anticipated by the cited reference. Several court decisions have affirmed and clarified the requirements for anticipation by emphasizing that the cited reference must not only disclose all the elements, but that they must be “arranged as in the claim.” *See Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983); *Net MoneyIN, Inc. v. VeriSign, Inc.*, No. 01-CV-441 (D. Ariz. Oct. 18, 2005). *Net MoneyIN, Inc.*, further spelled

out the requirements for anticipation by stating:

"The meaning of the expression 'arranged as in the claim' is readily understood in relation to claims drawn to things such as ingredients mixed in some claimed order. In such instances, a reference that discloses all the claimed ingredients, but not in the order claimed, would not anticipate, because the reference would be missing any disclosure of the limitation of the claimed invention "arranged as in the claim." But the 'arranged as in the claim' requirement is not limited to such a narrow set of 'order of limitation' claims. Rather, our precedent informs that the 'arranged as in the claim' requirement applies to all claims and refers to the need for an anticipatory reference to show all of the limitations of the claims arranged or combined in the same ways as recited in the claims, not merely in a particular order."

In *Net MoneyIN, Inc.*, the court cited *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452 (Fed Cir. 1984) and instructed that even if a cited reference contained all of the elements of a claim, if the cited reference was directed to a different device operating in a different way it did not anticipate the claim, as described below:

"Although the prior art reference could be said to contain all of the elements of the claimed invention, it did not anticipate under 35 U.S.C. § 102 because it 'disclose[d] an entirely different device, composed of parts distinct from those of the claimed invention and operating in a different way.'"

Net MoneyIN, Inc. also referenced *Ecolochem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361 (Fed. Cir. 2000) and reiterated that to anticipate a claim, a cited reference must offer a discussion that clearly linked its elements to that of the claim that is was said to anticipate, as described below:

"...we concluded that the reference could not anticipate the claimed invention because there was no link between that figure and the general discussion ... In another words, we concluded that although the reference taught all the elements of the claim, it did not contain a discussion suggesting or linking hydrazine with the mixed bed in the figure, and thus did not show the invention arranges as in the claim."

Net MoneyIN, Inc. further referenced the findings in *Connell v. Sears, Roebuck & Co.*, and concluded that "unless a reference discloses within the four corners of the document not only all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102."

Referring back to Burkinshaw, Applicants again point out that Burkinshaw does not teach each and every element of Applicants' claims. Burkinshaw also does not teach or suggest all the limitations arranged or combined in the same way as recited by Applicants' claimed invention and Burkinshaw does not link elements as claimed by Applicants. For example, Burkinshaw does not teach an artificial intervertebral disc. Just as in *Lindemann Maschinenfabrik GmbH*, in which it was ruled that a different device, composed of parts distinct from those of the claimed invention and operating in a different way does not anticipate a claim, Burkinshaw expressly teaches not only a different device, but one composed of parts distinct from Applicants' claimed invention and which are expressly described as operating in a different way. Burkinshaw expressly teaches a patellar prosthesis that is known to those skilled in the relevant field to operate in a different way from a prosthetic intervertebral disc. For example, a patella is part of a synovial joint and the patella is considered by those skilled in the art as bone comprised of hard tissue, meaning that a patellar prosthesis will be a device that replaces hard tissue (at a synovial joint). In contrast, those skilled in the relevant art know that an intervertebral disc is not part of a synovial joint. Indeed, it is known by those skilled in the relevant art that an intervertebral disc is comprised of substantially soft tissue soft, which means that an intervertebral disc prosthesis will be a device that replaces soft tissue.

Furthermore, as one would expect, nowhere in Burkinshaw is there anything expressly or implicitly linking the patellar prosthesis to another part of the body, such as vertebra, nor would one of ordinary skill in art link Burkinshaw's patellar prosthesis to any other part of the body. Burkinshaw also expressly teaches that its patellar prosthesis operate generally by requiring three components (see, e.g., Figs. 10, 13, 21, 23), which means that Burkinshaw's device not only operates in a different manner from that of Applicants' claimed invention, the Burkinshaw patellar prosthesis also clearly has parts distinct from and different than Applicants' claimed invention. It is further noted that nowhere in Burkinshaw is there anything expressly or implicitly linking its three component operation with any other type of operation, such as that claimed by the Applicants. Burkinshaw expressly teaches that its patellar prosthesis must operate by having one component articulate with a second component (*i.e.*, articulation surface 44 of Burkinshaw superior surface moves relative to fixation surface 74 of second component). This is contrary to the claimed invention in which the articulating surface is fixed relative to an inferior fixation surface. Burkinshaw also

expressly requires and operates with three articulating surfaces: articulating surface 44, inferior surface 44 articulating with slide surface 78, and articulation between articulation component 32 and base component 34 (*see, e.g.*, col. 2, lines 10-12; col. 3, lines 14-16; col. 4). Both articulation component 32 and base component 34 have superior and inferior surfaces. The patellar prosthesis of Burkinshaw is solely designed to be “affixed to patellar bone” (Abstract, col. 2, lines 1-10; claims). Thus, Burkinshaw does not teach or suggest a single articulating surface. Burkinshaw also does not teach or suggest a disc body having an inferior surface adapted for fixation to and is adjacent to vertebral bone. Moreover, Burkinshaw does not teach that any individual component of the patellar prosthesis operates separately at the patella. The Examiner appears to be trying to remove essential components in Burkinshaw, such as components 42 and 34, which would render the Burkinshaw device unoperable and unsuitable for its intended purpose. Accordingly, and contrary to the Examiner’s position, Applicants have shown that Burkinshaw does not teach or suggest each and every element of the claimed invention nor all the structural limitations of the claim and does not anticipate the claims.

In the outstanding Office Action, the Examiner asserts that the “device of *[sic]* is sized and configured and fully capable of being used in the disc.” (Office Action at p. 3). Applicant respectfully disagrees. Nowhere in Burkinshaw is there any support for this assertion and it is contrary to the fact that an intervertebral disc is comprised of substantially soft tissue soft, which means that an intervertebral disc prosthesis will be a device that replaces *soft tissue*. This is quite dissimilar to the present invention. As such, Applicants respectfully submit that the device taught by Burkinshaw would not be capable of being used similar to the claimed artificial intervertebral disc of the present invention. Further, Burkinshaw does not teach or suggest that the intervertebral disc prosthesis is in anyway adapted for fixation to a first vertebral bone surface. As such, the present invention is not only different in how it is intended to be employed, but also in its claimed structural limitations.

As stated in M.P.E.P. §2143, a basic requirement for a *prima facie* case of obviousness is that the prior art reference (or references when combined) must teach or suggest all the claim limitations. As the cited references do not teach or suggest the features of (i) an artificial intervertebral disc, (ii) a disc body having an inferior surface adapted for

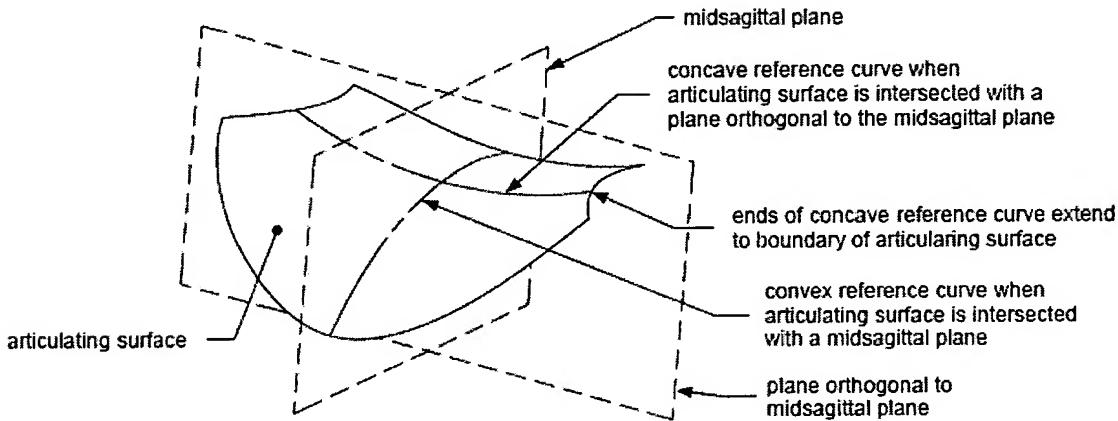
fixation to and is adjacent to a vertebral bone, or (iii) a single articulating surface, it is respectfully submitted the outstanding Office Action has not created a *prima facie* case of obviousness with regard to independent Claims 19, 31 and 42, and the claims dependent therefrom.

Accordingly, it is respectfully requested those rejections be withdrawn.

V. Anticipation under 35 U.S.C. § 102(b) By Shelokov

Claims 19, 21-32, 34-36 and 42 were rejected under 35 U.S.C. § 102(b) as anticipated by Shelokov. That rejection is respectfully traversed.

Applicants refer the Examiner to the claimed invention and reference a representative image of the articulating surface as illustrated below:



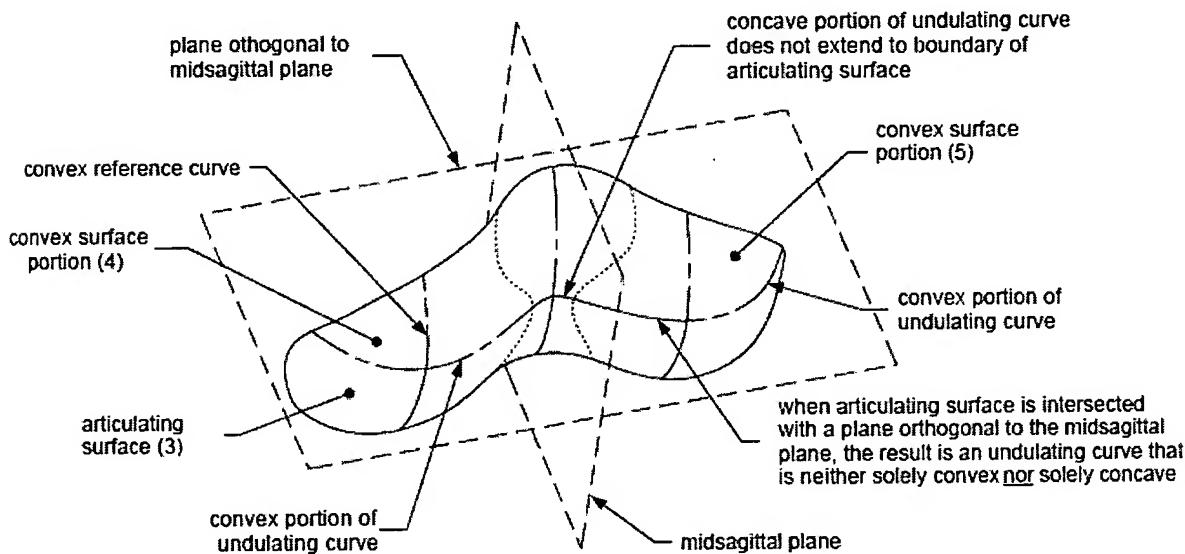
Applicants claim a superior surface that is substantially an articulating surface, wherein a solely convex reference curve having a substantially uniform radius of curvature is formed when the articulating surface is intersected with a midsagittal plane, wherein concave reference curves are formed when the articulating surface is intersected with planes orthogonal to the midsagittal plane, wherein the ends of the concave reference curves extend to boundaries of the single articulating surface. The claimed invention describes the articulating surface by concave reference curves in a first plane and convex reference curves in a plane orthogonal to the first plane. The claimed invention strongly contrasts with the device of Shelokov.

Contrary to the present invention which claims a convex reference curve having a

substantially uniform radius of curvature, Shelokov discloses “an outwardly curved arch, i.e., convex, having a varying radius of curvature” (col. 5, line 66 to col. 6, line 3). In a preferred embodiment, “the shape of the curve in the sagittal section will approximate the shape of a curve described by a Fibonacci mathematical series.” (col. 6, lines 7-9).

Further, Shelokov relies on a device that is expressly stated to have two articulating surfaces 3, 12 and the two articulating surfaces of Shelokov are, by express design, stated to operate and to articulate like a human knee. The human knee, like Shelokov’s device is a bimodal articulating surface and designed to sharply contrast with that claimed in the subject application.

A representative image of articulating surface 3 of Shelokov is illustrated below:



The figure above shows clearly that Shelokov does not teach an articulating surface that meets the requirements of Applicants’ claimed invention. For example, Shelokov’s articulating surfaces (3) is expressly shaped to represent the two condyles of the knee (col. 6, lines 1-21), represented above and in Shelokov’s specification and drawings as condyles (4, 5). For articulating surface 3, each condyle surface is convex; however when articulating surface 3 is intersected with a plane orthogonal to the midsagittal plane, the result is an undulating curve that is not solely convex or concave. Moreover, while a portion of the undulating curve is concave (when the surface is intersected with a plane orthogonal to the midsagittal plane), the concave portion is only a small portion in a center section and, hence, does not extend to the boundaries of articulating surface 3. In addition, at least two

articulating surface portions are required by Shelokov on a given disc body (3 or 12), which renders each surface of Shelokov as bimodal. Applicants articulating surface is not so arranged. Thus, it can be seen that the Shelokov device does not teach each and every element of the claimed invention nor all of the structural limitations of Applicants' claim and, therefore, cannot anticipate the claims.

Accordingly, it is respectfully requested that this rejection be withdrawn.

VI. Anticipation under 35 U.S.C. § 102(b) By Linscheid

Claims 19, 21-32, 34-36 and 42 were rejected under 35 U.S.C. § 102(b) as anticipated by Linscheid. That rejection is respectfully traversed.

Applicants respectfully submit that Linscheid does not teach each and every element of Applicants' claims. Linscheid also does not teach or suggest all the limitations arranged or combined in the same way as recited by Applicants' claimed invention and Linscheid does not link elements as claimed by Applicants. For example, Linscheid does not teach an artificial intervertebral disc. Just as in *Lindemann Maschinenfabrik GmbH*, in which it was ruled that a different device, composed of parts distinct from those of the claimed invention and operating in a different way does not anticipate a claim, Linscheid expressly teaches not only a different device, but one composed of parts distinct from Applicants' claimed invention and which are expressly described as operating in a different way. Linscheid expressly teaches a joint prosthesis for joints in which one bone is permitted a substantial degree of rotary circumduction with respect to the long bone and in particular for the trapezium and first metacarpal, which is the thumb joint (Col. 1). Linscheid further requires a two component prosthesis for replacing a joint between a long bone and a second bone. Those skilled in the art know that vertebra are not long bone. Those skilled in the relevant field also knows that a thumb joint operates in a different way than that of a prosthetic intervertebral disc. Those skilled in the relevant art know that a thumb joint is a synovial joint. It is also known by those of skill in the relevant art that an intervertebral disc is not a synovial joint. The bones that make up a thumb joint are bone comprised of hard tissue. This is contrasted with the intervertebral disc that is comprised of soft tissue. The mechanisms that allow for movement at a thumb is also known to be entirely different that that used around an intervertebral disc. Those skilled in the art further understand that a prosthetic joint at the

thumb is intended to replace hard tissue, which contrasts with what is known by those skilled in the art about a prosthetic intervertebral disc, which is known to replace soft tissue. Nowhere in the Linscheid reference is there anything expressly or implicitly linking the thumb joint prosthesis to another part of the body, such as vertebra, nor would those of ordinary skill in art ever link Linscheid's thumb prosthesis to any other part of the body. Linscheid expressly teaches that its thumb joint prosthesis operates and requires two components, the first member has "an enlarged head" and "an elongated stem that is appropriately sized and shaped to fit within the surgically exposed marrow recess in the proximal end portion of the first metacarpal" (col. 2, lines 36-42) and a second member that a proximally extending step and an enlarged head for bearing the articulating surface of the first member (col. 2, lines 46-52). The structures of Linscheid are expressly designed to replace bone (hard) tissue. This means that Linscheid's device not only operates in a different manner from that of Applicants' claimed invention, the thumb prosthesis of Linscheid also clearly has parts distinct from and different than Applicants' claimed invention. It is further noted that nowhere in Linscheid is there anything expressly or implicitly linking its two component operation with any other type of operation, such as that claimed by the Applicants. Linscheid expressly teaches that its thumb prosthesis must operate by having the first member articulate with the second member. Linscheid also expressly requires and operates with at least two articulating surfaces—one on the first member that articulates with a second articulating surface on the second member. Both first and second members have superior and inferior surfaces. By reading the Linscheid reference, it is clear that the joint prosthesis of Linscheid is designed solely as a thumb joint prosthesis (or any joint having bone arranged and operating exactly as those of a thumb joint). Thus, the evidence shows that Linscheid does not teach or suggest a single articulating surface. Linscheid also does not teach or suggest a disc body having an inferior surface adapted for fixation to and is adjacent to vertebral bone. Moreover, Linscheid does not teach a single articulating surface is fixed relative to the inferior surface. Accordingly, and contrary to the Examiner's position, Applicants have shown that Linscheid does not teach or suggest each and every element of the claimed invention nor all the structural limitations of the claim and does not anticipate the claims.

To this end, Applicants respectfully submit that none of the cited references, Burkinshaw, Shelokov, Linscheid and other cited documents, disclose all Applicants'

claimed elements nor do any of the cited references arrange or combine elements in the same way as recited in the claims nor do any of the cited references clearly link elements as claimed by Applicants. Thus, none of the cited documents can be said to anticipate the claimed invention. Because the cited references lack a teaching or suggestion of all claimed elements and lack a teaching or suggestion of arranging or combining all claimed elements as is arranged in the subject claims and do not teach or suggest linking elements as claimed by Applicants, this means the cited references also do not provide sufficient disclosure to render the claimed invention obvious.

Applicants respectfully submit that the invention as currently claimed is patentable and is distinct from Burkinshaw, Shelokov, Linscheid and the other cited references. Applicants have made a substantial showing of lack of anticipation and lack of obviousness. Accordingly, Applicants respectfully request the outstanding rejections be withdrawn and respectfully request the application be allowed to proceed to allowance.

CONCLUSION

In light of the arguments set forth above, Applicants respectfully submit that the Application is now in allowable form. Accordingly, Applicants respectfully request consideration and allowance of the currently pending claims.

A three month extension fee in the amount of \$555 and a request for continued examination (RCE) fee in the amount of \$405 are being paid by check attached herewith. It is believed that no additional fees are due. The Examiner is respectfully requested to call Applicants' Attorney for any reason that would advance the current application to issue. Please reference Attorney Docket No. 1003-1003.

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